Effective Date: October 12, 2011

## CRITERIA FOR PRIOR AUTHORIZATION

Pegloticase (Krystexxa®)

**PROVIDER GROUP:** Professional

**MANUAL GUIDELINES:** The following drug(s) requires prior authorization:

Pegloticase (Krystexxa)

## CRITERIA for pegloticase: (must meet all of the following)

• Patient must be 18 years of age or older.

- Patient must have a diagnosis of chronic gout that is refractory to conventional therapy (see attached table).
  - o Refractory to conventional therapies includes:
    - Patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with conventional therapy at the maximum medically appropriate dose or for whom these drugs are contraindicated.
- The dose does not exceed 8mg (one vial) every two weeks.

## Prior Authorization will be approved for 1 (one) year.

**NOTE:** No controlled trial data are available on the safety and efficacy of re-treatment with Krystexxa after stopping treatment for longer than 4 weeks. Due to the immunogenicity of Krystexxa, patients receiving re-treatment may be at an increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully.

**WARNING:** Anaphylaxis and infusion reactions have been reported to occur during and after administration of Krystexxa. Krystexxa should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Patients should be pre-medicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6mg/dL, particularly when 2 consecutive levels above 6mg/dL are observed.

It is recommended that patients at higher risk for G6PD deficiency be screened for G6PD deficiency before starting Krystexxa.

## **Conventional Gout Therapy**

Generic Name	Brand Name
Allopurinol	Zyloprim <sup>®</sup>
Febuxostat	Uloric®